

Remarks

In the Office Action, Claims 11, 19 and 24 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art. Claims 11-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 11-24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bombardelli (US Patent 5,637,302).

In this Amendment, Claims 11, 13, 19 and 23 have been amended, and Claims 25-27 have been added. It is believed that no new matter has been added, and that no subsequent search on the Examiner's part is necessitated by virtue of this Amendment. Claims 11-27 are pending.

A. ENABLEMENT REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 11, 19 and 24 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art.

Applicants have amended claim 11 to specifically recite an extract "consisting essentially of Ginkgo biloba plant part constituents." Applicants have also amended claim 19 to specifically recite a method of preparation of a water-soluble native dry Ginkgo biloba extract consisting essentially of Ginkgo biloba plant parts. Claim 24 depends from claim 19.

Applicants submit that amended claims 11 and 19 and claim 24 recite subject matter that is described in the specification in an enabling manner, as suggested by the Examiner, and Applicants accordingly, request withdrawal of the rejections to those claims under 35 U.S.C. § 112, first paragraph.

B. REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 11-24 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Specifically, the Examiner objected to the term "exclusively" in claim 1, and the terms "a drug" and "including a drug" in claim 13.

Applicants have further amended claim 11 to replace the term “exclusively” with the term “essentially” so as to conform with U.S. claim practice without thereby narrowing the scope of the claim. In addition, Applicants have amended claim 13 to remove the term “drug” and to recite that the extract includes a higher percentage of terpenolactones and flavoglycosides as compared with the Ginkgo biloba leaves from which the extract is extracted. Support for the amendment to claim 13 can be found in the specification, for example, at page 5, lines 5-8 of the translated specification. In addition, Applicants have amended claim 23 to remove alternative claiming language, which the Examiner may find objectionable (i.e., “in particular lipophile” and “in particular precipitation reactions, adsorption and desorption procedures, extraction procedures and the like”). Those features are now more properly recited in separate dependent claims (i.e., new claims 26 and 27). Applicants respectfully submit that the amendments to claims 11, 13 and 23 have overcome the Examiner’s specific objections to the claim language and respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

C. REJECTION UNDER 35 U.S.C. § 103(a)

Claims 11-24 were rejected under 35 U.S.C. §103(a) as being unpatentable over US Patent No. 5,637,302 to Bombardelli et al.

Bombardelli et al. describes a process for producing a purified extract from Ginkgo biloba leaves by solvent extraction with selected solvents. Bombardelli et al. teaches a procedure for purifying a crude extract of Ginkgo biloba leaves by subjecting the crude extract to a plurality of solvent extraction procedures in a fluid-fluid dispersion .

Claim 19 of the present invention recites a method of preparation of a water-soluble native dry Ginkgo biloba extract consisting essentially of Ginkgo biloba plant parts. The method includes, among other steps, the step of “ultrafiltration . . . through a filter with an average pore size ranging from 2000 to 10000 Daltons.”

Thus, the present invention provides a method that uses ultrafiltration in place of the series of solvent extractions in a fluid-fluid dispersion taught in Bombardelli et al., to arrive at a distinctly different product. For example, moderately polar components and high molecular

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constituents remain in solution with the Bombardelli et al. process, but would be removed in the method of the present invention through the ultrafiltration step recited in claim 19.

Furthermore, contrary to the Examiner's assertion, Applicants respectfully submit that it would not have been obvious to a person of ordinary skill in the art that the dry extract produced according to the process described at column 3, lines 1-21 in Bombardelli et al. is water-soluble as specifically defined in the Applicants' specification (e.g., page 1, lines 10-13). On the contrary, such plant extracts very often leave substantial insoluble residues (quite possibly caused by changes in the components), which are filtered out during the ultrafiltration feature of the present invention.

Moreover, as recited in the specification, extraction with n-butanol and toluene is "associated with the disadvantage of using organic solvents that might potentially constitute a health hazard." (See page 2, lines 9-15.)

Applicants respectfully submit that the invention recited in claim 19 is not taught or suggested by Bombardelli et al. for at least the reasons stated above. Applicants further submit that the inventions recited in dependent claims 20-24 and new claims 26-27, each of which includes all of the features of claim 19, are likewise not taught or suggested. Applicants accordingly request withdrawal of the rejections to claims 19-24 under 35 U.S.C. §103(a) and allowance of new claims 26-27.

Claim 11 of the present invention has been amended to recite a water-soluble, native dry extract consisting essentially of Ginkgo biloba plant part constituents and not including a solubilization agent. Claim 25 has been added to recite the extract of claim 11 wherein the extract does not include a galenic aid. Support for these changes is found in the original application, for example in canceled claim 1.

In accordance with the discussion relating to the method claims, Applicants further submit that the water-soluble, native dry extract recited in claims 11-18 and new claim 25 are likewise not taught or suggested by Bombardelli et al. Applicants accordingly request withdrawal of the rejections to claims 11-18 under 35 U.S.C. §103(a) and allowance of new claim 25.

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CONCLUSION

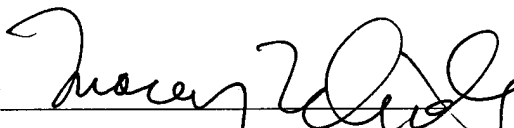
In view of the amendments made and arguments presented, Applicants respectfully submit that the presently pending claims are in condition for allowance.

A check in the amount of \$110.00 is enclosed for the fee due for a one (1) month extension of time. It is believed that no other fees are due for this submission. If it is determined that additional fees are due, or if any fee has been overpaid, the Commissioner for Patents is hereby authorized to charge said fees or credit any overpayment to Deposit Account No. 50-0552.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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